K041555

AUG - 9 2004

SecurView DX
510(k) Summary

Product Name: **SecurView DX**

Product Classification Name: Picture archiving and communication system

Product Classification Code: LLZ **CFR Section:** 892.2050

Classification Panel: Radiology **Class** II

Manufacturer: Hologic, Inc.
36 Apple Ridge Road
Danbury, CT 06810 USA

Contact Person: Gail Yaeker-Daunis
Telephone Number: (203) 731-8337
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Date Prepared: June 4, 2004

Predicate Device: K033400 Seno Advantage, General Electric Medical Systems

Device Description: The Hologic SecurView DX is mainly a software product. It is used for visualization and processing of digital radiology images. The SecurView DX is a multi-modality review workstation. It includes two high-resolution gray scale monitors (FDA cleared for Mammography), 3-button mouse, keyboard and workstation keypad. The software accepts images which have been created according to the "For Presentation" specification in the DICOM Standard. Image processing is external to the SecurView DX. The system will only use lossless compression or no compression at all when displaying mammography images.

The minimum computer requirements are:

Windows 2000® Operating System

Intel CPU with a clock rate of 2.0 GHz or greater

2.0 GB RAM or greater

140 GB Hard drive or greater, operating at 160 Mbs or greater

CD-ROM/R/RW, DVD +/-RW

10/100 Base TX Network Interface

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2004

Mr. Richard Follett
Vice President, RA/QA
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K041555
Trade/Device Name: SecurView DX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 4, 2004
Received: June 16, 2004

Dear Mr. Follett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) No. K041555

Indications For Use

Device Name: **SecurView DX**

The Hologic SecurView DX device is intended for selection, display, manipulation, filming and media interchange of multi-modality images from a variety of different modality systems. It also interfaces to various image storage and printing devices using DICOM or similar interface standards.

The device **used with FDA cleared monitors** may be used by a trained physician for display, manipulation and interpretation of **lossless compressed or non-compressed** mammographic images for screening and diagnostic mammography, as well as any other DICOM multi-modality image.

The SecurView DX is typically used by trained professionals, including, but not limited to physicians, radiologists, nurses, medical technicians and assistants.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041555